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WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*Allen, et. al. v. Takeda Pharmaceuticals  
North America, Inc., et al.*  
(Case No. 12-cv-00064)

MAGISTRATE JUDGE HANNA

**MEMORANDUM RULING:**  
**DR. SCOTT DELACROIX, UROLOGIC ONCOLOGIST**

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of Actos® and other drugs containing pioglitazone. Pending before this Court is the Defendants' Motion to Exclude Testimony of Plaintiffs' Expert, Dr. Scott Delacroix,<sup>1</sup> in which the Defendants seek an order precluding Dr. Delacroix from testifying as to both his general causation opinions and his specific causation opinions. Given the importance of these issues, this Court granted oral argument which was heard on December 12, 2013. This Court hereby adopts and incorporates herein the comments and explanations made by this Court at oral argument and for those reasons and those that follow, and those found within record document number 3771, the motion will be DENIED.

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<sup>1</sup> Rec. Doc. 3463. This motion has been urged on behalf of all named defendants in this matter. The Memorandum in Support of Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Dr. Scott Delacroix ["Memorandum"] is found at Rec. Doc. 3463-1. The Memorandum in Support of Plaintiffs' Opposition to Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Scott Delacroix, M.D. ["Opposition"] is found at Rec. Doc. 3604. The Reply in Support of Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Dr. Scott Delacroix ["Reply"] is found at Rec. Doc. 3694. For purposes of this motion, the Court will not distinguish among the various defendants as, for these purposes only, there is no legal distinction.

## EVIDENCE UNDER CHALLENGE

Dr. Delacroix has submitted two expert reports containing opinions that he has developed in this matter. His first report is addressed to the Plaintiffs' theory that Actos® can cause bladder cancer in human beings, *i.e.*, general causation, while his second report is addressed to his determination that Mr. Allen's bladder cancer was "caused," by his exposure to pioglitazone, *i.e.*, specific causation. The Defendants seek to have both of Dr. Delacroix's opinions stricken as inadmissible and/or unreliable for multiple reasons, which this Court will address below.

## LAW AND ANALYSIS

### I. APPLICABLE LAW

While state law governs the Plaintiffs' claims in this matter, the Federal Rules of Evidence control the admission of expert testimony.<sup>2</sup> Under the Federal Rules of evidence, "relevant" evidence is admissible, while irrelevant evidence is not admissible.<sup>3</sup> Evidence is "relevant" if it has any tendency to make a fact more or less probable than it would be without the evidence, and the fact being proven or disproven is of consequence in determining the action.<sup>4</sup> The party seeking to have expert opinion evidence admitted into evidence bears the burden of demonstrating, by a preponderance of the evidence, that the expert's findings and conclusions are based on the scientific method and, therefore, are reliable.<sup>5</sup>

The Federal Rules of Evidence require that a judge, faced with a proffer of expert scientific testimony, must begin by determining, pursuant to Rule 104(a), whether the expert is

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<sup>2</sup> *Huss v. Gayden*, 571 F.3d 442, 452 (5<sup>th</sup> Cir. 2009), citing *Mathis v. Exxon Corp.*, 302 F.3d 448, 459 (5<sup>th</sup> Cir. 2002).

<sup>3</sup> F.R.E. 402.

<sup>4</sup> F.R.E. 401.

<sup>5</sup> *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269, 276 (5<sup>th</sup> Cir. 1998) (*en banc*).

proposing to (i) testify to scientific knowledge (ii) that will assist the trier of fact to understand or determine fact in issue.<sup>6</sup> This will require a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts at issue.<sup>7</sup> This requirement is found in Rule 702 of the Federal Rules of Evidence, which reads as follows in its entirety:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

In the United States Supreme Court's landmark decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Court acknowledged the existence of a federal courts' gatekeeping role with regard to expert scientific opinion testimony, characterizing that role as one ensuring that such evidence meet the requirements of both reliability and relevance.<sup>8</sup> "Reliability" as discussed in *Daubert* refers to *evidentiary* reliability, *i.e.*, trustworthiness, rather than *scientific* reliability, which asks whether application of the principle produces consistent results, a distinction often blurred by Defendants' arguments. In a case involving scientific evidence,

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<sup>6</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592, 113 S.Ct. 2786, 2796, 125 L.Ed.2d 469 (1993).

<sup>7</sup> *Id.*, 509 U.S. at 592-93; *Moore*, 151 F.3d at 276.

<sup>8</sup> *Moore*, 151 F.3d at 275.

evidentiary reliability is based upon scientific validity, which asks whether the principle supports what it purports to show.<sup>9</sup>

The objective of this requirement is to make sure that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.<sup>10</sup> The Supreme Court identified several non-exclusive factors a Court should consider in determining whether proffered scientific opinion testimony is sufficiently reliable to permit admission into the record.<sup>11</sup> Those factors are:

- whether the expert's theory can be or has been tested;
- whether the theory has been subject to peer review and publication;
- the known or potential rate of error of a technique or theory when applied;
- the existence and maintenance of standards and controls; and
- the degree to which the technique or theory has been generally accepted in the scientific community.<sup>12</sup>

Several years later, the Supreme Court clarified when it held the gatekeeping role applied to all types of expert opinion testimony, not just scientific evidence, and revisited the reliability analysis.<sup>13</sup> Moreover, the Supreme Court reiterated that a court must have considerable leeway in deciding, in a particular case, how to go about determining whether particular expert

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<sup>9</sup> *Daubert*, 509 U.S. at 590 n.9.

<sup>10</sup> *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 152, 199 S.Ct. 1167, 1176, 143 L.Ed.2d 238 (1999). See also *Brown v. Illinois Cent. R. Co.*, 705 F.3d 531, 535 (5<sup>th</sup> Cir. 2013).

<sup>11</sup> See discussion, 509 U.S. at 594-595.

<sup>12</sup> *Moore*, 151 F.3d at 275.

<sup>13</sup> *Kumho Tire*, 526 U.S. at 141-142.

testimony is reliable.<sup>14</sup> Therefore, the test of reliability is flexible and there is no necessary or exclusive list of factors that must exist in order for a particular opinion to be admissible.<sup>15</sup>

*Daubert* makes clear that the factors it mentions do not constitute a definitive checklist or test. *Daubert* adds that the gatekeeping inquiry must be tied to the facts of a particular case. We agree with the Solicitor General that the facts identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of case categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.<sup>16</sup>

In the Fifth Circuit “[t]o determine whether proffered testimony is reliable, the trial court must make ‘a preliminary assessment of whether the reasoning or methodology underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’” *Brown v. Illinois Cent. R. Co.*, 705 F.3d 531, 535 (5th Cir. 2013) (quoting *Daubert* at 592–93). Further, “[t]o establish reliability under *Daubert*, an expert bears the burden of furnishing ‘some objective, independent validation of [his] methodology.’”<sup>17</sup> In doing so, “[t]he expert’s assurances that he has utilized generally accepted [principles] is insufficient.”<sup>18</sup>

In *Brown* the Fifth Circuit held that the trial court did not abuse its discretion where an expert testified that offered opinions were reliable merely upon and because of “education and

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<sup>14</sup> *Kumho Tire*, 526 U.S. at 152.

<sup>15</sup> *Id.* at 141-142, 149.

<sup>16</sup> *Id.* at 150 (citations and quotation marks omitted).

<sup>17</sup> *Brown*, 705 F.3d at 536 (quoting *Moore*, 151 F.3d at 276).

<sup>18</sup> *Id.* (quoting *Moore*, 151 F.3d at 276).

experience” and did not engage in or rely upon a credible methodology, particularly in the face of evidence in opposition to those opinions. Standing alone then, it is insufficient for an expert to base his or her opinion on education and experience alone, especially in the face of evidence to the contrary.

The Defendants’ Motion does not challenge the relevance of the challenged testimony, nor the qualifications of Dr. Delacroix.<sup>19</sup>

## II. ANALYSIS

### A. General Causation

Dr. Delacroix, as a urologic oncologist, has reviewed a considerable number of studies and publications, and has opined on general and specific causation; the following discussion will focus on **general causation**.

#### 1. Dr. Delacroix’s Report and Opinions

Dr. Delacroix’s first report is addressed to the Plaintiffs’ theory that Actos® can cause bladder cancer in human beings, *i.e.*, general causation. The report is fifty-five (55) pages in length, describes his professional background; contains an extensive discussion of the type of bladder cancer with which Mr. Allen was diagnosed; describes his methodology, which involves

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<sup>19</sup> The Defendants’ Reply dedicates a half-page to Dr. Delacroix’s apparent youth (his formal training as a physician ended in 2012), without including any actual argument suggesting that Dr. Delacroix is, therefore, unqualified because of his relative youth and does not tie this particular argument to any relevant *legal* issue, *i.e.*, the application of Rule 702. Considering the lack of actual argument, together with the lack of any argument about Dr. Delacroix’s qualifications in the Defendants’ original brief, this Court finds that the Defendants’ somewhat questionable discussion in the Reply brief as to Dr. Delacroix’s age is not intended to challenge Dr. Delacroix’s qualifications as an expert urologic oncologist. Furthermore, to the extent the rather dubious age-based discussion is intended as a formal challenge to Dr. Delacroix’s qualifications, this Court finds the argument made wholly without merit and boarding on the specious. As a general matter, age, in and of itself, does not, nor has it ever, qualified or disqualified an individual within his or her professional pursuits. At oral argument, the Defendants seemed to confirm they do not intend to challenge Dr. Delacroix’s qualifications as an expert urologic oncologist, notwithstanding the somewhat perplexing discussion as to his age contained in their written brief.

use of the Hill criteria<sup>20</sup> used in formulating his opinion as to causation; references certain epidemiological studies, and discusses pioglitazone and dual PPAR agonists generally; contains extensive discussions of fifteen epidemiologic studies and meta-analyses of such studies; and ultimately posits certain conclusions. Perhaps the more significant as to the challenges now argued by Defendants in the instant motion, are as follows:

- Pioglitazone is a class 2(a) carcinogen and appears to act both as a promoter as well as an inducer of carcinogenesis.
- Pioglitazone increases the risk for urothelial carcinoma of the bladder.
- Pioglitazone poses a risk for bladder cancer even in patients with short-term use.
- Carcinogens that act as promoters reduce the latency period for clinical detection of tumors.
- It is not scientifically valid to exclude serious adverse events, *i.e.* bladder cancers, from randomized clinical trial data. All bladder cancers detected after randomization should be formally and accurately reported in publications and subsequent analyses.
- The increased incidence of bladder cancer within one year of therapy, as seen in the PROactive study, are clinically relevant and point to pioglitazone acting as a promoter in patients with pre-existing risk factors for urothelial carcinoma of the bladder.

## **2. Rule 702/Daubert Factors**

After full review of all argument, evidence and supporting documentation, this Court finds the five illustrative factors noted below and identified in *Daubert* either, weigh in favor of admissibility of Dr. Delacroix's causation opinions and foundational underpinnings or do not weigh in favor of the exclusion of the challenged opinions and foundational underpinnings.

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<sup>20</sup> The Hill criteria are often used within the scientific community to assess a possible causal association, the Hill criteria are: 1. Temporal relationship; 2. Strength of the association; 3. Dose-response relationship; 4. Replication of the findings; 5. Biological plausibility (coherence with existing knowledge); 6. Consideration of alternative explanations; 7. Cessation of exposure; 8. Specificity of the association; and 9. Consistency with other knowledge. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, p. 600 (3d ed. 2011). Because there is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines, one or more factors may be absent or present even when a true causal relationship exists. *Id.* (citations omitted).



- **Testability.** Dr. Delacroix has testified, as a threshold matter, that the underlying foundational studies and the process he employed in generating his theory of general causation have been tested through the mechanism of clinical trials and other studies and the test results have demonstrated support for the foundational underpinnings of/for his theory. As a threshold matter, the testability of the foundational underpinnings of Dr. Delacroix's theory support a finding of admissibility. The absence of testing of the theory itself should not be fatal when acceptable methodology has been used and the underlying foundational underpinnings have been tested.
- **Peer Review.** Dr. Delacroix has cited to a great many peer-reviewed publications that provide scientific support for each element of his theory of causation. While it does not appear the *overall specific theory* of general causation posed in this matter, itself, has been subject to peer-review, this Court finds *the underlying studies* relied upon and incorporated and used as foundational supports for the theory, are and have been sufficiently subject to peer review and are accepted within the relevant scientific community. The absence of peer review of the actual overall theory of causation, in and of itself, should not invalidate Dr. Delacroix's opinion when otherwise accepted methodology has been employed upon peer-reviewed publications. Dr. Delacroix's heavy reliance on identified peer-reviewed publications, studies and information, as the foundational bases of/for his opinion lends strong support for the argument in favor of the admissibility of his opinion and foundational support for his conclusions, as a threshold matter.
- **Rate of Error.** Each underlying study relied upon by Dr. Delacroix has a rate of error attached to the theory or technique used and readily available for review and cross-examination. The absence of a rate of error as to the collective theory, itself, also, should not be fatal in the face of such error rates as to each underlying study.
- **Standards and Controls.** Dr. Delacroix is a qualified physician who has conducted his investigation and developed his opinions, in this matter, in compliance with the standards and controls under which he normally operates in his professional life. This Court finds that those standards and controls lend strong support for the argument of/for admissibility of Dr. Delacroix's opinions, as a threshold matter.
- **General Acceptance.** The overall theory that pioglitazone causes or promotes bladder cancer at the rate found by the Plaintiffs' experts does not appear to be generally accepted in the medical and scientific community, at this time. However, this fact does not, in and of itself, disqualify those theories if otherwise foundationally based in generally accepted studies and processes and grounded in sound methodology. Consequently, that fact alone, although significant, should not, standing alone, be determinative and does not, in and of itself, destroy the admissibility of Dr. Delacroix's opinions. Dr. Delacroix's process employed, conclusions reached, and opinions posited have been guided by scientifically accepted processes grounded within accepted scientific method, and stand upon a foundation of independent peer reviewed studies and articles. Consequently, this factor does not argue against allowing presentation to the trier of fact.



This Court, also, notes, that unlike in *Brown*, in the instant matter, the opinion(s) Dr. Delacroix offer(s) on [both] general [and specific] causation is [are] not based merely on his “education and expertise.” Dr. Delacroix relies on multiple studies, and publications, and extensive data and utilizes the Bradford Hill criteria in deriving his general causation opinion. Indeed, Dr. Delacroix applies each of the nine (9) Bradford Hill criteria—criteria which are both reliable and credible and under which he formulates his general causation opinion. Although the Defendants challenge his conclusion on the basis of contrary evidence to those studies and publications which form the underpinning of his opinion, the mere existence of evidence which might be argued in opposition to an opinion does not, in and of itself, render an otherwise arguably properly formulated and scientifically grounded opinion inadmissible.

Had Dr. Delacroix relied merely on his “education and experience” as did the expert in *Brown*, Defendants’ argument would be more persuasive, however, that is not the case. This Court finds Dr. Delacroix’s opinion does not fail the threshold test of *Brown* and, thus the Court will move to the more specific arguments and challenges made by Defendants.

### **3. *Prima Facie* Case**

This Court has conducted an exhaustive review of the briefs, the exhibits submitted in support of both parties’ arguments, and all studies and reports, including those specifically of Dr. Delacroix now under challenge. This Court finds, as a threshold matter, Dr. Delacroix is qualified to develop the opinions he has issued in this case, that as a threshold matter, he relied on standard and accepted scientific method(s) in formulating those opinions and again, as a threshold matter, the studies, publications and data which he relied upon were sufficiently reliable as to overcome Defendants’ threshold challenge. This Court further specifically finds, as a threshold matter, Dr. Delacroix’s reports and opinions demonstrate sufficient adherence to the

stringent standards he applies in his daily life as a physician and scientist as to meet Defendants' threshold challenge as to his methodology employed. For the foregoing reasons, and adopting the comments and explanation given by the Court at oral argument on December 12, 2013 and contained within the transcript of that hearing, as well as all reasons found within this Court's Ruling found in Doc. No. 3771, this Court finds the Plaintiffs have met their *prima facie* burden of demonstrating, as a threshold matter, that Dr. Delacroix's theory of *general causation* is admissible and finds Defendants' arguments on this issue are better suited to vigorous cross-examination.

### **DEFENDANTS' CHALLENGES**

This Court now turns its attention to Defendants' specific challenges. Initially, this Court suggests, the gravamen of the dispute between the Plaintiffs and Defendants as to Dr. Delacroix's *general causation* opinion, is much the same as presented in Defendants' Motion to Exclude Testimony of Plaintiffs' Experts that Actos can Cause Bladder Cancer Within One year of Use, which is the subject of a separate motion and Ruling, found in this Court's Ruling. [Doc. No. 3771] This Court's Ruling as to general causation, found in Doc. No. 3771, is hereby incorporated and adopted herein.

Defendants, in part, challenge the Plaintiffs' theory itself, and Dr. Delacroix's opinions, in large part, on the basis of an absence of testing, peer review, and the other *Daubert* factors, *as to the theory itself*, whereas, Plaintiffs focus upon the presence of testing, peer review, and other *Daubert* factors *as to the underlying studies forming the foundational legs of their theory*. Although inherent in the challenge to the theory, as a whole, might be challenges to the underlying studies, assumptions, and publications relied upon, Defendants do not, as clearly as might be desirable, make the necessary distinction between the two separate, but overlapping

conceptual challenges. Each argument is distinct; however, for the reasons given in greater detail in Doc. No. 3771, this Court has now found, under the facts of this case, the Plaintiffs have sufficiently made their *prima facie* case as a threshold matter, and that Defendants have not carried their burden to show, as a threshold matter, that Plaintiffs' experts' opinions must be excluded. Thus, for the reasons given within Doc. No. 3771, this Court found that Plaintiffs' experts' opinions have survived Defendants' threshold challenge as to *general causation*. Consequently, this Court adopts and incorporates that Ruling as part of its reasons herein as to Defendants' challenge to Dr. Delacroix's *general causation* opinion and will not reiterate that Ruling at this point. Consequently, Defendants' challenge to Dr. Delacroix's *general causation* opinion has been met by Plaintiffs and that portion of the motion is DENIED.

#### **B. Specific Causation**

Next, this Court turns its attention to Dr. Delacroix's opinions as to *specific causation*, as to the "cause" of Mr. Allen's particular type of bladder cancer.

Plaintiff Terrence Allen is currently 57 years old and has lived in Attica, New York for most of his life; he has worked in the nearby town of Batavia. Mr. Allen was recently laid off from a plumbing store where he unloaded trucks; prior to that, he worked at multiple hardware stores; prior to that he washed cars (early adolescence). Mr. Allen was first diagnosed with Type 2 diabetes mellitus in June 2002, at the age of 48. Dr. John Reilly, his primary care physician at that time, began treating Mr. Allen by prescribing Amaryl for his diabetes. Several years later, Dr. Reilly added a prescription for Metformin to the Amaryl Mr. Allen was taking. The following year (2006), Dr. Reilly prescribed Actos® to Mr. Allen for the first time and Mr. Allen, thereafter, began taking Actos®, *i.e.*, pioglitazone.

From 2002 through June 2006, Mr. Allen exhibited symptoms of uncontrolled erratic glycemic levels and experienced certain significant complications resulting from diabetes: heart attack, ulcerations of his toes, a toe amputation, etc. Two months after the Actos® prescription was issued by Dr. Reilly, Mr. Allen had an acute episode of blood in his urine. The parties vigorously dispute and contest the medical significance, nature, and diagnosis, if any, of this episode. However, the episode, itself, is an occurrence not without possible factual and legal relevance.

Dr. Reilly subsequently retired and Dr. Anna Lamb became Mr. Allen's treating physician. Dr. Lamb, upon assuming Mr. Allen's medical care, noted Mr. Allen had a high A1C level, resumed the prescription for Actos®, and prescribed insulin injections. Mr. Allen, thereafter, continued to take Actos®, however, with gaps in his Actos® prescriptions. Mr. Allen experienced a second acute episode of blood in his urine in January 2011, at age 57, and was, at that time, diagnosed with a large non-muscle invasive high grade papillary bladder tumor and benign prostatic hyperplasia. Surgery was performed immediately to excise the tumor; a second surgery was performed two months later and confirmed the entirety of the cancerous tumor had been removed. Mr. Allen's last prescription for Actos® was dated April, 2011. Mr. Allen continues to receive all necessary medical treatment and medical monitoring of his health.

#### **1. Dr. Delacroix's Opinion, Specific Causation**

First, it is significant to note Dr. Delacroix has not *treated* Mr. Allen at any time, rather Dr. Delacroix has *examined* Mr. Allen, and reviewed the relevant medical information and other evidence identified by him, in forming his medical opinions. Dr. Delacroix issued two opinions, the second directed to his opinion that Mr. Allen's bladder cancer was "caused," in part, by his exposure to pioglitazone. The eleven (11) page report indicates Dr. Delacroix reviewed "all of

the relevant medical records” concerning Mr. Allen; conducted an examination of Mr. Allen; considered Mr. Allen’s present and prior medical history, social history, and family history; considered Mr. Allen’s exposure to pioglitazone; and performed a differential etiology in an effort to determine the substantial cause(s) of Mr. Allen’s specific type of bladder cancer. Dr. Delacroix testified he concluded, to a reasonable medical certainty, that exposure to pioglitazone “caused” Mr. Allen’s bladder cancer,<sup>21</sup> and opines to a reasonable degree of medical and scientific certainty, pioglitazone is “the most significant and substantial modifiable risk factor to which Mr. Allen was exposed that led to development of Mr. Allen’s cancer.”<sup>22</sup>

In reaching this conclusion, Dr. Delacroix’s report reflects he considered, and ruled out, with reasons given, several other known and potential causes of bladder cancer: age; race; gender; diabetes; exposure to paint; exposure to well water (arsenic); exposure to second-hand smoke; the 2006 urinary tract infection; and other medications taken by Mr. Allen. Dr. Delacroix’s report contains a summary, an analysis, and the reasons for concluding that none of the alternative risk factors presented as large a risk of bladder cancer to Mr. Allen as did exposure to approximately 38,000 mg of pioglitazone, hence, Dr. Delacroix engaged in a differential etiology analysis in reaching his conclusions and formulating his opinion.

## **2. Rule 702/Daubert Factors**

The task for this Court, as the gatekeeper, is to determine whether Dr. Delacroix has the necessary qualifications, employs the required methodology, relies on scientifically acceptable evidence, and sufficiently comports with the inquiry and illustrative factors of *Daubert*, within his area of expertise, to be allowed to testify to the trier of fact, here the jury.

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<sup>21</sup> Memorandum, Ex. B3, Delacroix Dep. at 343:3-17. [Rec. Doc. 3472-1, p. 1349]

<sup>22</sup> Memorandum, Ex. C3 Delacroix Case Specific Report at 6 [Rec. Doc. 3472-1, p. 1850]

This Court finds that the five illustrative factors identified in *Daubert* either weigh in favor of admissibility of Dr. Delacroix's opinion as to *specific causation* or do not weigh in favor of its exclusion. This Court notes, Defendants directed much of their challenge to Dr. Delacroix's opinion, to an additional discussion of *general causation*, even when challenging Dr. Delacroix's *specific causation* opinion. Thus, this Court will address the arguments made by Defendants.

- **Testability.** Defendants' challenge the fact and Dr. Delacroix has admitted there is no test for determining whether Mr. Allen's bladder cancer was, in fact, caused, or promoted, by Actos®. This fact is neither unexpected nor unusual. If there were one such test, in all likelihood, our inquiry would be quite different. In and of itself, this point is not determinative, rather, reflects the medical and scientific dispute at hand. Also, the absence of testing of the theory itself should not necessarily be fatal when acceptable methodology has been used and the underlying foundational underpinnings have been tested.
- **Peer Review.** Dr. Delacroix has cited to many peer-reviewed publications he argues provide scientific support for his opinion that Mr. Allen's bladder cancer was "caused" by exposure to Actos®. While it does not appear the theory underlying *general causation* supporting Dr. Delacroix's opinion as to specific causation has been subject to peer-review, Dr. Delacroix indicated his opinion is formulated from/upon and with heavy reliance on peer-reviewed publications and studies. This Court notes for the reasons and findings made within Doc. No. 3771 that such foundational reliance on peer-reviewed material lends strong support for the argument for/of admissibility [of Dr. Delacroix's opinion,] as a threshold matter. The absence of peer-review of the theory itself should not be fatal when acceptable methodology has been used and the underlying foundational underpinnings have been peer-reviewed.
- **Rate of Error.** Each underlying study relied upon by Dr. Delacroix has a rate of error attached to the theory or technique used and is readily available for review and vigorous cross-examination. The absence of a rate of error as to the collective theory, itself, also, should not be fatal in the face of such error rates as to the underlying studies.
- **Standards and Controls.** Dr. Delacroix is a qualified physician, whose report indicates he has conducted his investigation and developed his opinions in this matter in compliance with the standards and controls under which he normally operates in his professional life. This Court finds those standards and controls lend strong support for the argument for/of admissibility of Dr. Delacroix's opinions.

- **General Acceptance.** The overall theory as to *general causation*, that pioglitazone causes or promotes bladder cancer at the rate found by the Plaintiffs' experts, upon which Dr. Delacroix's opinion as to *specific causation*, in part, relies, does not appear to be generally-accepted in the medical and scientific community, at this time. However, this fact does not, in and of itself, disqualify those theories, if otherwise scientifically sound and foundationally based on otherwise scientifically accepted studies and processes. Consequently, that fact alone, although significant, is not, standing alone, determinative and does not destroy the admissibility of Dr. Delacroix's opinions. Dr. Delacroix's process employed, conclusions reached, and opinions posited appear, facially, to have been guided by scientifically accepted processes facially grounded within accepted scientific method, and to stand upon independent peer-reviewed and testable studies and articles. Consequently, this factor does not argue against allowing presentation to the trier of fact, again, as a threshold matter.

### 3. *Prima Facie Case*

Again, as to *specific causation*, this Court has conducted an exhaustive review of the briefs, the exhibits submitted in support of both parties' arguments, and all studies and reports of Dr. Delacroix under challenge. This Court finds, as a threshold matter, Dr. Delacroix is qualified to develop the opinions he has issued in this case, that as a threshold matter, he relied on standard and accepted scientific method(s) in formulating those opinions and again, as a threshold matter, that which he relied upon was sufficiently reliable as to be admissible. This Court further finds, as a threshold matter, that Dr. Delacroix's reports and opinions demonstrate sufficient adherence to the stringent standards he applies in his daily life as a physician and scientist so as to meet Defendants' threshold challenge. For the foregoing reasons, and the reasons contained in Doc. No. 3771, adopted and incorporated herein, as well as comment and explanation made by the Court at oral argument and adopted and incorporated herein, this Court finds the Plaintiffs have met their *prima facie* burden of demonstrating that Dr. Delacroix's theory of *specific causation* is admissible as a threshold matter, and that Defendants' arguments as to Plaintiffs' *prima facie* case are better suited to vigorous cross-examination.



### C. The Defendants' Challenges

This Court will now turn its attention to Defendants specific challenges to Dr. Delacroix's *specific causation* opinions, arguing primarily, a failure to properly apply five (5) of the nine (9) Hill criteria.

#### 1. The Hill Criteria Generally

The instant motion presents a dispute which, primarily, focuses upon and is grounded within the scientific discipline of epidemiology, the study of whether there is a causal link between harm and a potentially harm-causing agent. Consequently, this Court looks to the Reference Manual on Scientific Evidence ["the Manual"] for guidance and illumination.<sup>23</sup> Specifically, the Manual notes epidemiology does *not*, in fact, *establish causation as a scientific fact*, rather it presents *processes and analysis off/to amass and address data for epidemiologists to consider, analyze, evaluate, and from which to draw conclusions, based upon their best judgment*.<sup>24</sup> Practitioners in this field agree that, in exercising their best judgment, one should consider nine factors identified by Sir Austin Bradford Hill (a British physician) in 1965:

- ***Temporal Relationship.*** The requirement that consequences occur after exposure to the harm-causing agent and not before.
- ***Strength of the Association.*** The relative risk that the agent will cause the consequence being studied.
- ***Dose-Response Relationship.*** Although not absolutely necessary, the existence of a dose-response relationship is a strong indication that the agent is causing the effect.
- ***Replication of the Findings.*** The more often the results have been replicated, the stronger the results are deemed to be.
- ***Biological Plausibility.*** Whether the current theory is consistent with existing knowledge.

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<sup>23</sup> REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (3d. ed. 2011), hereinafter referred to as "the MANUAL."

<sup>24</sup> MANUAL, at 598.

- ***Consideration of Alternative Explanations.*** An epidemiologist who reaches one conclusion and refuses to consider any others has found a weak association, at best.
- ***Cessation of Exposure.*** If the reverse dose-response relationship also exists, *i.e.*, the cessation of exposure results in a reduction of the incidence of the effect, then the causal relationship is very strong.
- ***Specificity of the Association.*** Is the effect of the type that can be caused by this agent?
- ***Consistency with other knowledge.*** Non-scientific knowledge can sometimes be relevant to the epidemiological search for data on causation.

## **2. The Individual Hill Criteria**

It is accepted the Hill criteria are criteria meant to guide, and are not requirements from which the absence of one or more is meant to be fatal; with that in mind, this Court will look to the individual criteria and Defendants' challenge to each.

### **A. Temporal Association**

Once again, the Defendants challenge made to *specific causation* contains much of the same argument, also, made as to *general causation*. Defendants, again, argue and steadfastly focus upon the generally-accepted premise that bladder cancers cannot develop in less than one year, and thus, argue, generally, any cases of bladder cancer which developed within the first year of exposure to pioglitazone are not relevant to the inquiry and, in particular, are not relevant to the PROactive clinical trial and other clinical studies relied upon by Plaintiffs' experts, and, therefore, must be excluded from consideration, and thus, Plaintiffs' theory as to *general causation* must fail, causing Dr. Delacroix's opinion as to *specific causation* to, also, fail. The Defendants, again, argue their theory as to *general causation*, *i.e.*, that those cases of bladder cancers presenting within one year or less of exposure to pioglitazone cannot have been caused by Actos® and, therefore, must be excluded from any analysis; with those cases excluded, Defendants' experts are adamant there is no statistically-significant association between

pioglitazone and bladder cancer and therefore, there can be no *general* causation and therefore, there can be no *specific* causation. Plaintiffs' experts argue the same cancer cases not only should not be excluded, but *must be included* and must be considered in any analysis, as those very cases *establish* the statistically significant association between pioglitazone and bladder cancer. Defendants rely upon the generally accepted theory of cancer development; Plaintiffs' experts posit a different, however, not wholly unprecedented theory of/for development or promotion of cancer, and thus, significance of/for those, heretofore, excluded cases. Again, these arguments are essentially the same arguments made by the Defendants in their challenge to the Plaintiffs' *general causation* theory that bladder cancer can be caused within one year of exposure to Pioglitazone, and those arguments made by the Plaintiffs' in response. This Court, again, rejects Defendants' argument for the same reasons articulated in the Memorandum Ruling on the Plaintiffs' theory of general causation and incorporates and adopts those reasons and findings found in Doc. No. 3771 and, also, notes this Court's comments and explanation given at oral argument as further support.

### **3. Consistency of Results**

The Defendants' next challenge as to Dr. Delacroix's *specific causation* opinion is, again, to Dr. Delacroix's *general causation* opinion, but, again, argued within their challenge to his *specific* causation opinion. Defendants argue several studies Dr. Delacroix cited in his General Causation Report allegedly do not consistently demonstrate the same causal association to which Dr. Delacroix has opined.<sup>25</sup> Again, within the relevant scientific discipline, this Court is guided

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<sup>25</sup> This Court notes Defendants' argument as to Dr. Delacroix tended to conflate Dr. Delacroix's opinions to general causation and specific causation. The Court notes, of course, that should Plaintiffs' theory as to general causation fail, as a matter of course, any opinion as to specific causation grounded upon that theory, also, must fail. However, the Court, also, notes the two inquiries are not wholly the same; such a tendency to conflate the two is problematic to a thorough analysis of the issues at hand.

by the Hill criterion of consistency which asks, among other questions, whether the results of a study have been replicated. In theory, the more often the study results are replicated, the more reliable those results are. The discipline suggests the replication element/factor is quite significant when looking toward a general consensus on a possible or probable causal relationship between agent and effect; however, as the authors of the Manual recognize, reliability does not necessarily turn on whether a study has been replicated by the time trial commences, nor necessarily does the legal standard at play.<sup>26</sup> Also, this Court finds the mere existence of a result, which can be argued as inconsistent, does not, in and of itself, render an opinion necessarily unreliable scientifically or inadmissible, legally. One-hundred percent agreement is so rare within human endeavor, whether in matters great or small, as to be almost unheard of, and certainly admissibility does not impose such an unrealistic requirement. Rather, *admissibility* within the law, our inquiry here, rests upon scientific *reliability* which, also, does not embrace the stringent standard argued by Defendants. An expert who finds studies which, arguably, are inconsistent with other studies and his or her opinions, ideally, should consider those inconsistent studies in preparing his or her opinions and present his or her reasons for his or her conclusions reached. Consistency is certainly desirable, but differing results and opinion are not disallowed. Dr. Delacroix's report contains ample evidence he considered the entire scientific picture before him, considered both supporting and, arguably, inconsistent evidence, and developed opinions that are explained by the evidence he finds persuasive, and explained the evidence he finds unpersuasive, and gives his reasons why. Again, this Court notes that, once

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<sup>26</sup> "It is important that a study be replicated in different populations and by different investigators before a causal relationship is accepted by epidemiologists and other scientists." MANUAL at 604. However, "[t]his may not be the legal standard..." *Id.* at note 163. (Citing *Smith v. Wyeth-Ayerst Labs Co.*, 278 F.Supp. 2d 684, 710 n.55 (W.D.N.C. 2003) (observing that replication is difficult to establish when there is only one study that has been performed at the time of trial.)).

again, there are two distinct inquiries afoot, with distinct and differing underlying processes, goals, and rationales at play, which are being conflated by Defendants' arguments. One involves the formulation of opinion, the other the examination of the opinion. One plays a significant role in science and, therefore, is strong fodder for cross-examination in determining the other – however, the two goals are not one and the same – a distinction not, it would seem, fully appreciated within Defendants' argument.

This Court, also notes, certain of Defendants' remaining arguments as to Dr. Delacroix's opinions raise concern for the Court. For instance, Defendants argue, "Dr. Delacroix's report cites to a number of studies that reached, arguably, inconsistent results, and importantly, the *majority* of those studies show no statistically significant increased risk of bladder cancer with Actos® use."<sup>27</sup> The Defendants' argument, however, focuses on Dr. Delacroix's discussion of only *one* of the fifteen studies and meta-analysis he considered, specifically, the Bosetti meta-analysis, and seems to argue Dr. Delacroix's consistency analysis is based *solely* on the Bosetti paper, while ignoring his full discussion of the other fourteen papers. Such disturbing and blind argument, regrettably, is not unique to Defendants' arguments and is not helpful to the Court or Defendants' argument, as it acts to undercut the credibility of the argument(s) made. This Court found nothing in Dr. Delacroix's report or deposition to justify the Defendants' argument as made; to the contrary, Dr. Delacroix's report indicates his consistency finding relies primarily on multiple studies *other* than the Bosetti paper argued by Defendants. Regrettably, the noted example is not unique: the Defendants' suggestion that Dr. Delacroix "retreated from his own criticism"<sup>28</sup> is another example of highly questionable selective argument in the face of the

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<sup>27</sup> Memorandum, at 9-10 (emphasis in original).

<sup>28</sup> Memorandum, at 10.

reality of Dr. Delacroix's report and testimony, as does the suggestion Dr. Delacroix "qualified his answer and applied different criteria to similar studies,"<sup>29</sup> as well as the argument Dr. Delacroix "cherry-picks" studies in order to formulate his opinions.<sup>30</sup> Dr. Delacroix might not give the answer Defendants desire, but that is an expert's prerogative. Dr. Delacroix might not embrace the studies Defendants champion, but he explains that choice. If such an explained choice is to be considered, "cherry-picking," as Defendants argue, then Defendants' experts would likely be equally guilty as well. These and other equally problematic arguments fail to demonstrate such inconsistency as to render Dr. Delacroix's opinions unreliable. Consequently, this Court finds Defendants' arguments on those points unpersuasive.

An expert is free to rely upon those studies he or she believes to be significant and distinguish others he or she does not – he or she is, however, not permitted *to ignore* accepted scientific and/or medical evidence and merely opine based upon his or her underlying education or training.<sup>31</sup> However, Dr. Delacroix does not violate this standard, rather, he embraces the standard by giving full explanation for and of his selections and opinions; the fact the Defendants' might disagree with his choices and explanations is fodder for cross-examination, not exclusion. Again, those arguments of Defendants which are grounded in the actual opinions made and actual facts at hand, and not a rather questionable blind selection of those facts and opinion, are better directed to vigorous cross-examination.

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<sup>29</sup> Dr. Delacroix explained that he held the Takeda and Azoulay studies to different standards because they are different kinds of studies, an explanation that, on its face, does not appear unreasonable. *See* Defendants' Exhibit B3 (Delacroix Dep.) at 316-318.

<sup>30</sup> Memorandum, at 11-12.

<sup>31</sup> *Brown*, 705 F.3d at 535.

#### 4. Strength of Association

The Defendants, also, challenge the strength of the association Dr. Delacroix found between exposure to pioglitazone and bladder cancer, without actually addressing Dr. Delacroix's findings as to that issue and his explanation of those findings. Specifically, Dr. Delacroix relies on six studies which he opines establish such an association. While the strength of the association varies significantly among those six studies, none fails, altogether, to suggest an association.<sup>32</sup> The Defendants do not address Dr. Delacroix's actual reasoning, but rely, instead, on *the variation* in strength of association among the studies discussed and, again, place their focus, primarily, within the context of the Bosetti paper to argue that Dr. Delacroix's *entire* conclusion is unreliable.<sup>33</sup> However, in addition to addressing evidence which does not seem applicable to the relevant portion of Dr. Delacroix's opinion challenged or to the actual argument Defendants made, Defendants, again, argue a standard well above that required within the applicable law as to any expert, and, again, at best, present an argument better directed to vigorous cross-examination. This Court is unpersuaded by Defendants' suggestion that *the variation* in the relative risk findings among the various pioglitazone studies upon which Dr. Delacroix relies, renders his conclusions wholly unreliable, as opposed to merely the subject for vigorous cross-examination at trial.

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<sup>32</sup> Defendant's Exhibit C2, at 45-46.

<sup>33</sup> For reasons that are unclear to this Court, the Defendants invoke a chart showing relative risk estimates that is not one on which Dr. Delacroix seems to have relied in reaching his final conclusion(s). Instead, the chart contains information that is reflected within one of the meta-analyses that Dr. Delacroix describes in his Report. This Court cannot determine whether the Defendants' argument constitutes a simple misreading of Dr. Delacroix's report or, on the other hand, whether the argument was made to add "smoke and mirrors" to the analysis of the issue at hand. Nonetheless, the Court is once again perplexed and concerned by the nature of Defendants' argument made.



## 5. Specificity

Defendants' argument as to specificity, it would seem, centers upon a confusing at best, and, quite perplexing understanding and application of the Hill criterion. The specificity requirement within the Hill criterion does *not* limit causation findings to only those instances where a particular agent *causes*, and is the *only* possible cause of, a signature disease,<sup>34</sup> but rather requires strong skepticism when *one* agent is alleged to cause *many different* types of disease.<sup>35</sup> In this case, the Plaintiffs' argument alleges that pioglitazone causes bladder cancer and nothing more. Therefore, the Plaintiffs do not seem to have created the doubt as to the specificity of the causal link asserted and argued by Defendants. The Defendants' argument as to this point is wholly without merit.

## 6. General Causation

In their Reply brief, the Defendants raise new challenges to Dr. Delacroix's alleged selective reliance upon certain newly-argued studies. The arguments made by Defendants are both cryptic and, again, quite perplexing. For example, the challenge to Dr. Delacroix's reliance upon a study known as the Neumann Study, consists of two sentences that do not illuminate the alleged unreliability of the study in any way:

Only by omitting almost a quarter million study participants, can Neumann show a statistically significant relationship between Actos® and bladder cancer. Plaintiffs do not mention that [] when all of the patients over 40 were included in the analysis, including the more than 230,000 patients older than 79, there was no significant relationship between Actos® and bladder cancer.<sup>36</sup>

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<sup>34</sup> See Memorandum, at 14 ("As there is nothing unique about the attributes of bladder cancers that occur in Actos users as distinguished from those in the general population unexposed to Actos, there is no 'specificity' under the Bradford Hill criteria.").

<sup>35</sup> MANUAL, at 605-06.

<sup>36</sup> Reply, at 5.

The argument made suggests Defendants wish to argue some aspect of the Neumann study they dislike or with which they disagree, however, they have not identified the *legal* or *scientific* issue(s) at play. Defendants do not identify who is omitting participants, nor why or when such omission occurred or the alleged effect, expected, intended, or otherwise, for or of the suggested omission. Furthermore, the Defendants have not provided relevant discussion of Dr. Delacroix's use of the Neumann study, nor of how Dr. Delacroix's understanding and use of that study should render his conclusions unreliable. In the absence of some relevant context or explanation for the cryptic argument made, this Court cannot discern the essence of Defendants' challenge and, therefore, finds it is an argument wholly without merit as presented. Regrettably, similar deficiencies exist as to the remaining challenges; Defendants' remaining challenges are cryptic at best as to certain other studies relied upon by Dr. Delacroix.<sup>37</sup> Nonetheless, this Court finds these rather cryptic and random arguments, also, do not demonstrate any improper reliance by Dr. Delacroix and do not demonstrate his specific causation opinion to be unreliable. In other words, the Reply Brief, also, does not demonstrate legal or scientific unreliability in Dr. Delacroix's methods, analysis, or conclusions, but, at best, foreshadows possible bases for what this Court anticipates will be a lively, extensive, and thorough cross-examination at trial.

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<sup>37</sup> For example, this Court notes the KPNC study is incomplete and consequently, likely should be used with great caution, if at all, when arguing either for or against any conclusion at this point in time; the IARC publication is not definitive in either direction because it reported both a finding that "Pioglitazone was classified as probably carcinogenic to humans...", and that the group "was unable to consistently rule out confounding and bias related to disease severity and detection" (Reply at 5; Reply, Exhibit 1, at 807); and the Bosetti study is similarly undefinitive ("There is, however, an overall 20% excess risk of bladder cancer in relation to pioglitazone use, with somewhat higher risks for longer duration of use," but "there are no clear biological mechanisms that can explain the apparent increase in bladder cancer risk in pioglitazone users. Moreover, our findings indicate that the association between pioglitazone and bladder cancer is modest and can therefore be due to other sources of bias or residual confounding in observational studies." Reply, Exhibit 2, at 5-6).

## 7. Specific Causation Itself

Finally, the Defendants direct challenge directly to the methodology used by Dr. Delacroix in reaching his conclusion that Mr. Allen's bladder cancer was, to a reasonable medical certainty, caused by Actos®. A significant proportion of the Defendant's argument consists of assertions and argument that Dr. Delacroix has ignored, or "largely disregarded" the alternative risk factors that could have caused Mr. Allen's bladder cancer,<sup>38</sup> together with assertions that Dr. Delacroix failed to prepare a differential etiology.<sup>39</sup> This Court finds this argument of great concern. This Court notes even a cursory review of Dr. Delacroix's Reports and testimony reveals Dr. Delacroix *did conduct* the very differential etiology analysis that the Defendants argue is absent and, also, shows that, in so doing, he considered all of the alternative risk factors Defendants argued he ignored.<sup>40</sup> Disagreeing with a differential etiology is not basis for argument that the differential etiology was not conducted, and Defendants are, again, cautioned as to such selective and blind argument. This Court finds Dr. Delacroix did conduct a differential etiology and did consider the argued risk factors Defendants' challenge. Therefore, Defendants' argument on this point is completely without merit and borders on specious.

The Defendants, also, argue, alternatively, this Court will assume, that Dr. Delacroix did not simply disregard the other risk factors, rather, he "failed to appropriately evaluate them,"<sup>41</sup>

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<sup>38</sup> See Memorandum, at 16; Reply, at 9-10 ("Plaintiffs Ignore Mr. Allen's Multiple Risk Factors For Bladder Cancer").

<sup>39</sup> MANUAL, at 617.

<sup>40</sup> See Defendants' Exhibit C3, at 7-10, wherein Dr. Delacroix considers age, race, gender, diabetes, exposure to paint, exposure to well water (arsenic), exposure to second hand smoke, urinary tract infection, and exposure to other medications.

<sup>41</sup> Memorandum, at 17.

and that he must “thoroughly investigate” the alternative risk factors before ruling them out.<sup>42</sup> Again, this Court cautions Defendants as to making unsupported arguments in the face of undisputed factual evidence to the contrary; disagreeing with the conclusions of a process is not basis for argument that the process did not occur. As Defendants admit within their own argument, Dr. Delacroix did, in fact, engage in a differential etiology; it would seem Defendants merely disagree with his conclusions. Dr. Delacroix did evaluate the alternate risk factors; Defendants, it would seem, merely disagree with that evaluation; Dr. Delacroix did investigate, it would seem Defendants merely disagree with the nature of that investigation, - disagreement with does not equate to an absence of. This Court has read Dr. Delacroix's report thoroughly and reviewed portions of his depositions and finds Dr. Delacroix did engage in a differential etiology; that the differential etiology is sufficiently thorough to allow him to testify as to that differential etiology before the trier of fact and; therefore, survives Defendants’ threshold challenge.

The Defendants’ arguments, also, seem to suggest Dr. Delacroix should be held, again, to a higher legal standard, one requiring *definitive proof* of *specific* causation; however, the standard established and embraced under New York law is one of a “*substantial cause*” *proved to a reasonable degree of medical certainty*, not, as Defendants seem to argue, one of definitive and absolute proof. As such, the Plaintiffs need only demonstrate by a preponderance, the existence of a specific “substantial” cause of Mr. Allen’s bladder cancer.<sup>43</sup> Defendants’ arguments are, at best, misplaced in the face of settled New York law.

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<sup>42</sup> Memorandum, at 19.

<sup>43</sup> *N.Y. Pattern Jury Instruction* -- Civil 2:70 (3d ed. 2013).

The majority of the Defendants' Reply argument concerning Dr. Delacroix's specific causation opinion consists of an effort to demonstrate that the Plaintiffs have not proven Mr. Allen's cancer developed by way of genetic mutation – again, an argument pivotal to the analysis of *general causation* and one fully discussed by this Court in Doc. No. 3771. This Court will not reiterate that discussion at this point, but adopts and incorporates that discussion and findings herein. Of course and again, this Court recognizes that within *general causation* if the trier of fact were to agree with the Defendants and Defendants' experts' argument that genetic mutation is the sole process by which bladder cancer can manifest, Defendants likely would prevail on *general causation* and, if so, on *specific causation* as well; however, should the trier of fact agree with Plaintiffs and Plaintiffs' experts' argument and opinion that another process accounts for Mr. Allen's cancer, then Plaintiffs likely would prevail as to *general causation* and the inquiry would then proceed to *specific causation*. Nonetheless, whether the battle is fought on the battlefield of specific or of general causation, it remains a medical and scientific debate waged between and among qualified members of their relevant medical and scientific disciplines, using what, on their face, appear to be accepted and reliable processes, and based upon what appear, on their face, to be underlying sufficiently reliable medical and scientific studies and evidence, albeit with grossly differing conclusions and contradictory focuses being employed. As such, this Court finds the dispute among otherwise qualified experts is one for the trier of fact and not the gatekeeper – one for vigorous cross-examination and not for threshold exclusion.<sup>44</sup>

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<sup>44</sup> As to fact specific, specific causation, defendants do not seem to argue within this motion, the possible factual finding that Mr. Allen's cancer developed within one year of exposure to pioglitazone – Mr. Allen experienced blood in his urine within the first year of taking pioglitazone. Rather, when this point was discussed within oral argument, defense counsel suggested he was unaware of that fact; nor was it argued within the written motion. Consequently, it does not seem Defendants' raise a challenge based on this disputed factual issue within their challenge to Dr. Delacroix's opinion as to *specific causation*. Thus, this Court makes no determination or comment of any nature as to that vigorously disputed factual issue.

### III. EVIDENTIARY HEARING

The Defendants requested this Court agree to hear live testimony from the experts prior to ruling on the instant motion; this Court carefully considered the Defendants' request. The decision of how to go about ruling on the instant motion is squarely within this Court's discretion.

The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether and when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert's relevant testimony is reliable. Our opinion in Joiner makes clear that a court of appeals is to apply an abuse-of-discretion standard when it reviews a trial court's decision to admit or exclude expert testimony. That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion. Otherwise, the trial judge would lack the discretionary authority needed both to avoid unnecessary "reliability" proceedings in ordinary cases where the liability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises. Indeed, the Rules seek to avoid unjustifiable expense and delay as part of their search for truth and the just determination of proceedings.<sup>45</sup>

This Court reviewed the extensive briefing provided by both parties, as well as the large number of exhibits, including expert reports, depositions, and other documents, and concluded the nature of the challenges presented and the arguments made did not illustrate a need for live testimony. Live testimony would not be likely to contribute to any greater understanding of the nature of the dispute than can be and has been found in a careful reading and analysis of the briefs and accompanying evidence and documentation. The request for an opportunity to present live testimony in an evidentiary hearing is DENIED. However, in recognition of the importance of these issues to both the Defendants' and Plaintiffs' cases, this Court allowed oral argument, which was held on December 12, 2013 and this Court hereby incorporates into the instant ruling

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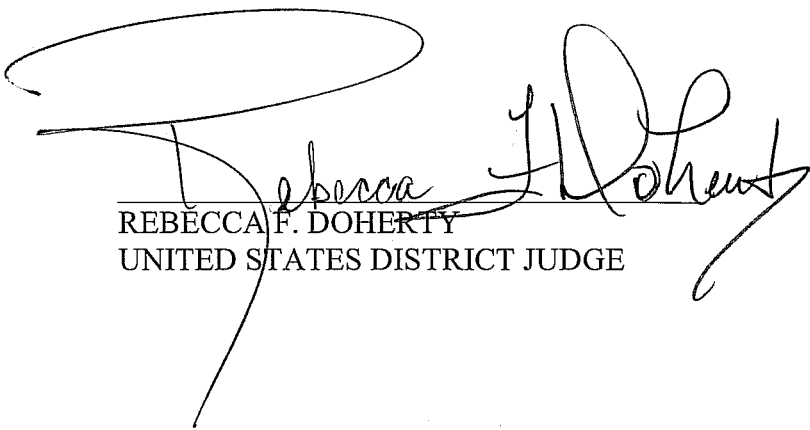
<sup>45</sup> *Kumho Tire*, 526 U.S. at 152-53 (emphasis in original) (citations and quotations omitted).

this Court's comments and explanations, and support contained in and as reflected in the Transcript of Oral Argument heard on December 12, 2013.

**CONCLUSION**

For the foregoing reasons, the Defendants' Motion to Exclude Testimony of Plaintiffs' Expert, Dr. Scott Delacroix, shall be DENIED as to both general and specific causation.

THUS DONE AND SIGNED this 20 day of December, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE